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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/529,450	03/28/2005	Karsten Eulenberg	052317-1010	8928

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EXAMINER	
CHOWDHURY, IQBAL HOSSAIN	
ART UNIT	**PAPER NUMBER**
1652	

DATE MAILED: 12/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/529,450	EULENBERG ET AL.	
	Examiner	Art Unit	
	Iqbal Chowdhury, Ph.D.	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-36 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-36 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

This application is a 371 of PCT/EP03/10973 filed on 10/2/2003.

Claims 1-36 are pending.

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group, I claim(s) 1 (in part), 8, 9, 11-12, 13, 14, 15, 33 (in part), 34 (in part), drawn to a pharmaceutical composition comprising Mipp1 homologous protein or fusion protein.

Group, II claim(s) 1 (in part), 2-7, and 10, 11, 12, 13, 14, 15, 26 (in part), 20, 21, 33 (in part), 36, drawn to a pharmaceutical composition comprising isolated polynucleotide comprising Mipp1 homologous protein.

Group, III claim(s) 1, 11, 12, 13-15 (in part) and 34 (in part), drawn to a modulator or effector of Mipp1 homologous protein or fusion protein.

Group, IV claim(s) 1, 10, 11, 12, 13-15 (in part) and 34 (in part), drawn to a modulator or effector of Mipp1 homologous polynucleotide.

Group, V claim(s) 16-17, 28, 30, 32, drawn to a method of use of polynucleotide encoding Mipp1 homologous protein for the manufacture of a medicament for the treatment of metabolic diseases or dysfunctions.

Group, VI claim(s) 16-17, 27, 28, 29, 30, 32, drawn to a method of use of polypeptide of Mipp1 homologous protein for the manufacture of a medicament or composition for the treatment of metabolic diseases or dysfunctions.

Group, VII claim(s) 16-17, 28, 30, 32, drawn to a method of use of modulator of Mipp1 homologous protein for the manufacture of a medicament for the treatment of metabolic diseases or dysfunctions.

Group, VIII claim(s) 16-17, 28, 30, 32, drawn to a method of use of modulator of polynucleotide of Mipp1 homologous protein for the manufacture of a medicament for the treatment of metabolic diseases or dysfunctions.

Group, IX claim(s) 27, 29, drawn to a method of use of an agent which modulate the interaction of polypeptide Mipp1 homologous protein to its targets for the preparation of a pharmaceutical composition for the treatment of metabolic diseases or dysfunctions.

Group, X claim(s) 18, 19, 35, drawn to a non-human transgenic animal exhibiting a modified expression of a Mipp1 homologous polypeptide and hexakisphosphate kinase polypeptide.

Group, XI claims 22, drawn to a method of identifying polypeptide involved in the regulation of energy homeostasis.

Group, XII claims 23, drawn to a method of screening agents, which modulates the interaction of a Mipp1 with a target molecule.

Group, XIII claims 24, drawn to a method of screening agents, which modulates the activity of Mipp1 homologous protein.

Group, XIV claims 25-26, drawn to a method of producing a composition comprising a compound which modulates the activity of a polypeptide Mipp1 homologous protein with a pharmaceutical acceptable carrier, diluent and /or adjuvant.

Group, XV claims 25-26, drawn to a method of producing a composition comprising the agent which modulate the interaction of polypeptide Mipp1 homologous protein with target molecule with a pharmaceutical acceptable carrier, diluent and /or adjuvant.

Group, XVI claims 31, drawn to a method of use of host cells for the preparation of a medicament.

Group, XVII claims 33, drawn to a kit comprising Mipp1 antibody.

Group, XVIII claims 33, drawn to a kit comprising Mipp1 antisense oligonucleotide.

For each inventions I-XVIII above, restriction to one of the polypeptide from Table 1 is also required under 35 U.S.C. 121 and 372. Therefore, election is required of one of inventions I-XVIII **and** one polypeptide from Table 1.

2. The inventions listed as Groups I - XVIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The composition comprising polynucleotide encoding a polypeptide Mipp1 homologous polypeptide of Group II, the composition comprising polypeptide Mipp1 of Group I, modulator or effector of Mipp1 homologous protein of Group III, modulator or effector of Mipp1 homologous nucleic acid of

Group IV, non-human transgenic animal of Group X, a kit comprising Mipp1 antibody of XVII and a kit comprising Mipp1 antisense oligonucleotide of Group XVIII, are each unrelated and distinct entities. The only shared technical feature of these groups is that they all relate to polynucleotide encoding a polypeptide Mipp1 homologous polypeptide. However, this shared technical feature is not a "special technical feature" as defined by PCT Rule 13.2 as it does not define a contribution over the art. According to the search report (PCT form 210), a DNA encoding a Mipp1 is known in the art (Caffrey et al. "The human and rat forms of multiple inositol polyphosphate phosphatase: functional homology with a histidine acid phosphatase up-regulated during endochondral ossification", FEBS Lett. 1999 Jan 8; 442(1): 99-104). Thus, a DNA encoding a Mipp1 polypeptide does not make contribution over the prior art.

3. A method of identifying polypeptide involved in the regulation of energy homeostasis of Group XI does not share any "special technical feature" with Group II as the polynucleotides of Group II are neither made nor used by the method of identifying polypeptide involved in the regulation of energy homeostasis of Group XI.

4. A genetically altered non-human transgenic animal of Group X does not share any "special technical feature" with Group I as the polypeptide of Group I and genetically altered non-human animal of Group IX are independent and distinct.

5. The polypeptide of Group I does not share any technical feature with methods of Groups V, VIII, IX, and XVI as polypeptide of Group I neither made nor used by the methods of Groups V, VIII, X, and XVII.

6. The polynucleotide of Group II does not share any technical feature with methods of Groups VI, VII, IX, XI, XII, XIII, XIV and XV as polynucleotide of Group II neither made nor used by the methods of Groups VI, VII, IX, XI, XII, XIII, XIV and XV.

7. The methods of Groups V, VI, VII, VIII, IX, XI, XII, XIII, XIV, XV and XVI do not have unity of invention with each other as each methods comprises unrelated steps, use different products and produce different effects.

8. The nucleic acid sequences encoding the proteins and proteins of Table 1 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions represent structurally different polypeptides and polynucleotide encoding them. Therefore, where structural identity is required, such as for hybridization or expression or antibody binding, the different sequences have different effects.

37 CFR 1.475 does not provide for multiple products and/or methods within a single application. Therefore, inventions of Group I – XVIII lack unity of invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP §

821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Iqbal Chowdhury whose telephone number is 571-272-8137. The examiner can normally be reached on 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 703-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Respectfully,

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